

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : David C. Turner Confirmation No.: 6090
Appln. No. : 09/921,192 Art Unit : 1791
Filed : August 2, 2001 Examiner : WOLLSCHLAGER, Jeffrey Michael
Title : METHOD FOR COATING ARTICLES BY MOLD TRANSFER

ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS' BRIEF (37 C.F.R. 1.192)

This Appeal Brief is an appeal from the final rejection mailed January 28, 2009, a Notice of Appeal having been submitted on April 28, 2009.

Authorization to pay the fees required under Section 1.17(f) is submitted herewith.

This brief is transmitted in triplicate. (37 CFR 1.192(a))

This brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

1. REAL PARTY INTEREST

The real party in interest of the subject patent application is Johnson & Johnson Vision Care, Inc, having a principal place of business at 7500 Centurion Parkway, Suite 100, Jacksonville FL 32256.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences pending.

3. STATUS OF THE CLAIMS

Claims 1-3, 6, 8-11, 14-20, 23-26, 31, 32, 34-41 and 52-87 stand rejected and are appealed. Claims 4, 5, 7, 21, 22 and 33 have been canceled. Claims 12, 13, 27-30 and 42-51 have been withdrawn. Claims 1-3, 6, 8-11, 14-20, 23-26, 31, 32, 34-41 and 52-87 are being appealed.

4. JURISDICTIONAL STATMENT

The Board has jurisdiction under 35 U.S.C. 134(a). The Examiner mailed a final rejection on January 28, 2009 setting a three-month shortened statutory period for response. The time for responding to the final rejection expired on April 28, 2009. A notice of appeal was filed on April 28, 2009. The time for filing an appeal brief expires on June 28, 2009. The appeal brief is being filed on June 29, 2009. As June 28, 2009 was a Saturday, the brief is timely filed under 37 CFR 1.7.

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6. STATUS OF AMENDMENTS

Claims 1-3, 6, 8-20, 23-32 and 34-87 are pending. The amendments filed on November 13, 2008 have been entered.

7. SUMMARY OF THE CLAIMED SUBJECT MATTER

The claims of the present invention relate to a method for manufacturing coated articles via mold transfer. According to the method of the present invention, high molecular weight (greater than about 300 kD) coating compositions are applied to a molding surface of a mold or a mold half. Specification, page 2, lines 10-12, and page 3, lines 25-26. The coating composition comprises at least one polymer selected from the group consisting of poly(vinyl alcohol), polyethylene oxide, poly(2-hydroxyethyl methacrylate), poly(acrylic acid), poly(methacrylic acid), poly(maleic acid), poly(itaconic acid), poly(acrylamide), poly(dimethylacrylamide), carboxymethylated polymers, polystyrene sulfonic acid, polysulfonate polymers, polysaccharides, glucose amino glycans, block or random copolymers thereof, or mixtures thereof. Page 6, lines 12-21. After the mold is coated with the coating solution a monomer mixture comprising, a silicone-containing hydrogel monomer is dispensed into the mold or mold half; (page 10, lines 1-4, page 16, lines 22-24) and the mold containing the monomer mixture is cured. Page 16, lines 26-28. The curing step is started within 5 minutes of dispensing the monomer mixture into the mold (page 16, line 28- page17, line 2) and the polymer does not

chemically attach to the article. Page 2, lines 16-18. The dwell time may also be less than 45 seconds (claim 31 and page 17, line 1-2). The claims further recite that the article is a contact lens (claim 31, page 3, line 3-5)

8. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

The rejection of claims 1-3, 6, 8, 52-54, 56-59, 61 and 62 as unpatentable under 35 U.S.C. 103(a) over Winterton et al. (US 6,719,929) in view of Martin et al (US6,039,899).

The rejection of claims 9 and 10 as unpatentable over Winterton et al. in view of Martin et al. and Li et al (US 6,565,776).

The rejection of claim 11 as unpatentable over Winterton et al. in view of Martin et al. and Soye et al (US 5,316,700).

The rejection of claims 14-18, 23, 64-66, 68-71 and 74 as unpatentable over Winterton et al. in view of Martin et al. and Yang et al (US5,397,848) and Lohmann et al (US 6,169,127).

The rejection of claims 19 and 20 as unpatentable over Winterton et al. in view of Martin et al. and Yang et al., Lohmann et al., and in further view of Turner et al. (WO 01/27662).

The rejection of claims 24 and 25 as unpatentable over Winterton et al. in view of Martin et al., Yang et al. Lohmann et al and Li (US 6,565,776).

The rejection of claim 26 as unpatentable over Winterton et al. in view of Martin et al., Yang et al. Lohman et al., Li et al. and Soye et al.

The rejection of claims 31,32,36,38,76-78, 80-83, 85 and 86 as unpatentable over Winterton et al. in view of Martin et al. and Vanderlaan et al.

The rejection of claims 34 and 35 as unpatentable over Winterton et al. in view of Martin et al. and Vanderlaan et al. and Turner et al.

The rejection of claim 37 as unpatentable over Winterton et al. in view of Martin et al. and Vanderlaan et al., Yang et al. and Holguin et al. (US6,706,836).

The rejection of claims 39 and 40 as unpatentable over Winterton et al. in view of Martin et al., Vanderlaan et al. and Li et al.

The rejection of claim 41 as unpatentable over Winterton et al. in view of Martin et al., Vanderlaan et al., Li et al. and Soye et al.

The rejection of claims 55, 60 and 63 as unpatentable over Winterton et al. in view of Martin et al., and Narducy et al. (US 4,963,159).

Examiner has rejected claims 67, 72 and 75 as unpatentable over Winterton et al., Martin et al., Yang et al, Lohmann et al. and Narducy et al.

The rejection of claims 67, 72 and 75 as unpatentable over Winterton et al., Martin et al., Yang et al, Lohmann et al. and Narducy et al.

The rejection of 79, 84 and 87 as unpatentable over Winterton et al., Martin et al., Vanderlaan et al. and Narducy et al.

9. STATEMENT OF FACTS

In rejecting claims 1-3, 6, 8-20, 23-32 and 34-87, the Examiner has relied for every rejection on Winterton et al. in view of Martin et al. The following additional references Vanderlaan et al., Li et al., Soye et al., Naducy et al., Yang et al. and Lohmann et al. in various combinations.

Winterton et al. discloses a method for coating contact lenses with polyionic material(s) via applying the coating to the mold before forming a lens therein. Abstract. Winterton et al. discloses the coating is applied in successive layers of alternating charge. Col. 15, lines 38-49. Winterton et al. also discloses using a single solution containing both polymers with polyanionic and polycationic charge. Col. 14, lines 42-51. The layers of the coating are held in place by the charge associations between layers of cationic and anionic charge. Winterton et al. disclose that the polyionic materials "will typically have a molecular weight Mn of about 10,000 to about 150,000". Col. 13, lines 62-63. Winterton et al further discloses that "if the increase in

molecular weight is too substantial, the difficulty in handling may also increase.” Col. 13, lines 59-61. Winterton et al. does not disclose that the monomer mixture should be subjected to a dwell time before curing.

Martin et al. discloses an automated apparatus and processes for making contact lenses. Abstract. The apparatus and process provide “continuous or at least semi-continuous automated manufacturing, line to provide high speed, high volume production.” Col. 3, lines 39-42. Multiple lens molds are collected in a pallet for processing. Col. 6, lines 52-54 and Figure 7(a). Martin et al. discloses that an accumulator section is used to hold a number of lens pallets to enable batch processing at precure. Col. 32, lines 51-65. Martin et al. does not disclose or suggest any process or conditions for forming a coated lens. Martin et al. is silent as to the properties, such as molecular weight, for a coating material.

Vanderlaan et al. discloses “contacting at least one surface of a medical device with a coating effective amount of a carboxyl-functional polymer and . . . at least *one coupling agent*”. Column 1, lines 39-42. (emphasis added). The coatings are bound to the substrate surface via ester or amide linkages. Abstract. The carboxyl-functional polymers may be of any molecular weight. Col. 2, lines 32-33. Molecular weights between 100,000 and 10,000,000 g/mol. are disclosed. Col. 2, lines 33-34. The article formed first and then contacted with the coupling agent and the polymer. Col. 4, lines 37-43. Preparation 1 of Vanderlaan et al. discloses making an uncoated silicone hydrogel contact lens, which is then coated by contacting the formed lens with a coating solution and a coupling agent (Example 1). Col. 6, lines 1-10.

Li et al. discloses “using inorganic material to coat the optical surfaces and sidewalls of mold parts made from clear-resin materials”. Abstract. The coating materials protect “the clear resin from interaction with otherwise reactive monomers from which the molded article is made, such coatings can also be used to achieve preferential release.” Abstract. The coatings of Li et al. are permanent and non-transient. Col. 3, lines 58-63. The protective coatings of Li et al. are non-reactive with the lens material. Col. 6, lines 34-35 and lines 66-67. Thus the coatings of Li et al. remain on the lens mold and do not become part of the contact lens.

Many of the effective coating materials disclosed by Li et al. are inorganic. Col. 7, lines 1-18. Li et al. does not disclose a process for making coated contact lenses, coating polymers having a molecular weight of greater than about 300 kD or dwell times of less than 5 minutes.

Soye et al. discloses a process and apparatus for removing excess lens forming material. Abstract. The apparatus of Soye et al. provides a "cavity for excess lens forming material with at least two openings and producing differential gas pressure across the opening to remove excess lens forming material." Soye et al. abstract. Soye et al. does not disclose methods for forming coated contact lenses. Soye et al. also does not disclose any properties for a lens coating material, or any process conditions useful for making a coated lens.

Narducy et al. discloses a process for making colored contact lenses. Abstract. In the process of Narducy et al. at least a portion of a formed lens is coated with a color coat which contains a binding polymer. Col. 4, lines 4-6. Applying the color coat to the lens mold is not disclosed. Narducy et al. also does not disclose the molecular weight of the binding polymer. Narducy et al. discloses that the color coat also contains a solvent. Col. 5, lines 4-9. Narducy et al. discloses ethanol as a solvent and ethyl lactate as a cosolvent. Col. 5, lines 10-13.

Lohman et al. discloses coating an article via "after-glow plasma-induced polymerization of a polymerizable unsaturated compound on the substrate". Col. 7, lines 4-5. Lohman et al. teaches that the "expressions 'polymerizable unsaturated compound' and monomer are used . . . synonymously". Col 7, lines 23-25. Lohman et al. further discloses at column 11, lines 5-15 that hydroxyethylmethacrylate is a suitable monomer which may be used in the after-glow plasma-induced coatings disclosed therein. Thus, Lohman et al. discloses a reactive process for forming coatings from reactive monomers. Lohman et al. also discloses that the substrate "includes any material conventionally used for the manufacture of biomedical devices, e.g. contact lenses, which are hydrophilic per se, sans reactive groups, e.g. amine or hydroxyl groups are inherently present in the material and therefore also at the surface of a biomedical device . . . but suitable materials may also be based on other underlying monomers or polymers having reactive groups." Column 10, lines 16-29. Thus, Lohman et al. does not suggest using any

polymeric material as a coating composition. Instead Lohman et al. discloses forming a polymeric coating, by polymerizing reactive monomers onto a lens surface which has reactive groups.

Yang et al. discloses methods for incorporating hydrophilic constituents into silicone polymer materials". Col 1, lines 44-45. The hydrophilic constituents are "preferably substantially uniformly distributed in the silicone polymer material". Col. 1, lines 51-52. The hydrophilic components include "a hydrophilic portion and a silicone polymer portion." Col. 1, lines 64-66. Yang et al. does not disclose polyHEMA. Yang instead discloses silicone-polyHEMA copolymers, which contain "silicone polymer portions of sufficiently high molecular weight so as to facilitate physical immobilization." Col. 3, lines 27-31. Poly(acrylic acid), poly(methacrylic acid) and poly(hydroxyethyl methacrylate) are examples of hydrophilic groups which may be used as the hydrophilic portion of a silicone-hydrophilic copolymer. Col.9, lines 33-32.

Turner et al. discloses processes for coating a hydrophobic contact lens substrate with a hydrophilic coating material. Abstract. The "coatings are prepared and applied as aqueous solutions, suspensions, or colloids and then applied to the substrate", page 8, lines 5-7. The substrate disclosed in Turner et al. is "coated with coating that will have a surface area expansion factor greater than one. Page 3, lines 20-21.

Holguin et al. discloses a method for preparing poly 2-hydroxyethyl methacrylate and pressure sensitive adhesives. Abstract.

10. ARGUMENTS

Claim 6 and 31 are independently patentable.

Claims 1-3, 6, 8, 52-54, 56-59, 61 and 62 are patentable under 35 U.S.C. 103(a) over Winterton et al. (US 6,719,929) in view of Martin et al (US6,039,899) and Vanderlaan et al. (US 6087415).

The Examiner has rejected claims 1-3, 6, 8, 52-54, 56-59, 61 and 62 as unpatentable under 35 U.S.C. 103(a) over Winterton et al. (US 6,719,929) in view of Martin et al (US6,039,899) and Vanderlaan et al. (US 6087415).

Examiner stated that

-“Winterton et al. teach a method for coating a contact lens comprising coating a mold with a polymeric material having a high molecular weight . . . dispensing a monomer mixture comprising a silicone containing hydrogel mixture into the coated mold . . . and curing the monomer mixture and the coating to attach/entrap the coating composition to the contact lens”;

-“Martin et al disclose an automated method of producing a contact lens in a fast, efficient and precise manner having a dwell time within the claimed range”. Page 3, January 28, 2008 rejection;

-Winterton et al. do not teach the coating composition has a molecular weight of greater than about 300 kD. However, Vanderlaan et al. teach that hydrophilic coatings for contact lenses . . . are suitable and preferably employed in a molecular weight range from about 100,000 to at least about 1,000,000. Page 4, January 28, 2008 rejection.

Winterton et al. discloses a method for coating contact lenses with polyionic material(s) via applying the coating to the mold before forming a lens therein. Abstract. The polyionic materials of Winterton et al. are applied either in successive layers of alternating charge, (col. 15, lines 38-49) or using a single solution containing polymers with both polyanionic and polycationic charge. Col. 14, lines 42-51. The layers of the coating are held in place by the charge associations between layers of cationic and anionic charge. Because the coating is held in place largely by charge interaction, very high molecular weights are not required. Winterton et al. disclose that the polyionic materials “will typically have a molecular weight Mn of about 10,000 to about 150,000”. Col. 13, lines 62-63. Winterton et al further

discloses that "if the increase in molecular weight is too substantial, the difficulty in handling may also increase." Col. 13, lines 59-61. Winterton et al. does not disclose that the monomer mixture should be subjected to a dwell time before curing.

Martin et al. discloses an automated apparatus and processes for making contact lenses. The process includes steps to form the contact lens molds, filling the lens molds and polymerizing the hydrogel. Abstract and Figure 1. Martin et al. does not disclose or suggest any process or conditions for coating a lens mold or forming a coated lens. Martin et al. is silent as to the properties, such as molecular weight, for a coating material.

The claims of the present invention recite a process for mold transfer coating articles, such as contact lenses. The process of the present invention "does not rely on specific reaction chemistries for attachment of the coating to the lens, as do other known coating methods." Page 2, lines 15-17. Claim 1 recites that the coating polymer has a molecular weight of greater than about 300 kD. Because the coatings of the present invention do not rely on reaction chemistries for attachment, the coatings must have a molecular weight "sufficiently high so as to avoid dissolution of the coating into the monomer mixture used." Page 3, lines 15-16. The process must also be carefully controlled to allow the monomer mix to soften and intercalate into the coating polymer without dissolving the coating polymer.

"Dwell time, or the elapsed time from which the monomer mixture is dispensed into the mold until curing commences is critical because the coating composition is soluble in the hydrogel and silicone-containing hydrogel monomer mixtures. Dwell time must be less than about 5 minutes and preferably is less than about 45 secs". Page 16, line 28 – page 17, line 2.

Thus, the claims of the present invention disclose two elements which are neither disclosed nor suggested by Winterton et al. combined with Martin et al.: a coating polymer having a molecular weight of at least about 300 kD and a dwell time of less than about 5 minutes.

To cure this deficiency, Examiner further relied upon Vanderlaan et al. However, Vanderlaan et al. discloses chemically attaching a polymer coating to a preformed contact lens via reaction with a coupling agent. See Example 1 and col. 1, line 39-42 “contacting at least one surface of a medical device with a coating effective amount of a carboxyl-functional polymer and . . . at least *one coupling agent*”. This is a completely different coating process than the process disclosed in present invention or Winterton et al. and the Examiner has provided not any explicit reasoning why one of skill in the art would select the isolated teachings of Winterton et al., Martin et al. and Vanderlaan et al. as the Examiner has done.

This, however, does not establish a legally sufficient *prima facie* obviousness rejection. “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 437-438 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)); *see also* MPEP § 2143.01(IV) (“A statement that modifications of the prior art to meet the claimed invention would have been ‘well within the ordinary skill of the art’ at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.”) (emphasis in original) (citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

The Examiner, however, merely concludes that the skilled artisan would select the recited coating polymers, the recited molecular weights, and the dwell time from among those known in the art. The Examiner has failed to provide sufficient reasoning to support his rationale as to why one of skill in the art would select the recited elements from disparate teachings of Winterton et al., Martin et al. and Vanderlaan et al. For example, the Examiner has not provided any explicit reasoning why one would adopt the coating process of Winterton et al., but would replace the polyanionic/polycationic coating polymers having molecular weights between

10,000 - 150,000 with the carboxyl functional polymers (without the coupling agents) disclosed in Vanderlaan et al., which have molecular weights between 100,000 and 10,000,000. If one were going to combine the teachings of the references, why would one of skill in the art, considering Winterton et al. and Vanderlaan et al. not choose a molecular weight between 100,000 and 150,000 in the range where the disclosures of the two references overlap? Why would one choose to increase the molecular weight and coat via mold transfer (as disclosed in Winterton et al.), instead of using a coupling agent (as disclosed in Vanderlaan et al.)? And finally, how would anyone of skill in the art know that a dwell time was critical with polymers having the recited molecular weight when both Winterton et al. and Vanderlaan et al. are silent with respect to this process condition? Why would someone of skill in the art, considering mold transfer coating an article, consider Martin et al. at all, when Martin et al. discloses an integrated process for forming lens molds and contact lenses and is completely silent as to the steps or conditions for forming coated articles? Neither the cited references nor the Office Action itself answers these questions. Absent explicit reasoning to support the basis for the specific modification or combination, the alleged modification or combination cannot support a *prima facie* obviousness rejection.

It is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). At best, the Action has proffered a collection of references that mention the various elements in isolation. This, however, does not establish a legally sufficient *prima facie* obviousness rejection. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, (2007) (“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”).

Reversal of the rejection of claim as unpatentable over Winterton et al., in view of Martin et al. and Vanderlaan et al. is requested.

Claims 2-3, 6, 8, 52-54, 56-59, 61 and 62 depend from claim 1, and are patentable over Winterton et al., in view of Martin et al. and Vanderlaan et al. for the reasons articulated above. Reversal of the rejection of claims 2-3, 6, 8, 52-54, 56-59, 61 and 62 as unpatentable over Winterton et al., in view of Martin et al. and Vanderlaan et al. is requested.

Claim 6 further recites that the dwell time is less than about 45 seconds.

With respect to claim 7, Martin et al. is silent as to any process for making a coated contact lens, the desired properties of the coating polymer (such as molecular weight), or curing conditions for the coated lens (such as a dwell time of less the 45 seconds). Martin instead discloses automated method and apparatus for the continuous or semi-continuous production of contact lenses.

As noted in the prior response, Martin et al. also discloses

“Accumulator section 168 includes a holding mechanism 166 that is timed by a control means (not shown) to halt a lead pallet in place on the conveyor 32(c) and enable a predetermined number of subsequent pallets to assemble behind the halted lead pallet to enable batch processing at the procure apparatus. In the preferred embodiment, twelve pallets are accumulated enabling up to ninety-six (96) mold assemblies to be processed at the precure apparatus 60 in a batch mode for an extended period of time of 30 to 60 seconds while continuously receiving new pallets from the production line at a rate of 1 every 6 to 12 seconds.” Column 32, lines 51-65.

The purpose of the accumulator is to *delay* the pallets from entering the cure tunnel. This delay insures that the pallets being accumulated do not push the pallets already in the cure tunnel out before they are done, or do not create a jam in front of the cure tunnel which would result in pallets being pushed from conveyor. Had Martin et al. appreciated the criticality of the dwell time specified in the present application, they clearly would not have suggested an intentional *delay* in curing the mold assemblies. Applicants also note that Martin et al. does not disclose how long it takes to get the lenses from the filling step 107 to the curing step 110, and that the

other steps, such as clamping and transporting the mold assemblies need to be considered in determining the dwell time of the Martin et al. process. Martin et al. does not disclose how long these steps take.

According to Martin et al. the accumulator holds new pallets until 12 are accumulated. If pallets arrive every 6 to 12 seconds, that means the lenses can be held at the accumulator from between 72 to 144 seconds. Examiner has stated that the “timeframe takes the maximum number of lenses suggested by Martin et al, into account (“up to ninety-six”). In this “up-to” embodiment, about half of the lenses would continue to have a dwell time of less than about 45 seconds.” What Martin et al. says is: “twelve pallets are accumulated enabling *up to ninety-six (96) mold assemblies* to be processed at the precure apparatus”. Col. 32, lines 61-62. The phrase “up to” refers to the number of mold assemblies in each pallet, not the number of pallets being collected in the accumulating section. Even if each pallet is half full, the lenses will still be held in the accumulating section for the time periods disclosed in Martin et al. (72 to 144 seconds).

The cited references recognize neither the problem nor the solution identified by the Applicants, namely that “[d]well time, or the elapsed time from which the monomer mixture is dispensed into the mold until curing commences is critical because the coating composition is soluble in the hydrogel and silicone-containing hydrogel monomer mixtures.” Page 16, lines 28-31.

It is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). At best, the Action has proffered a collection of references that mention the various elements in isolation. This, however, does not establish a legally sufficient *prima facie* obviousness rejection. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, (2007) (“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”).

Applicants respectfully submit that claim 7 is patentable over the combination of Winteron, et al., Vanderlaan et al. and Martin et al.

With respect to claim 7, Martin et al. is silent as to any process for making a coated contact lens, the desired properties of the coating polymer (such as molecular weight), or curing conditions for the coated lens (such as a dwell time of less the 45 seconds). Martin instead discloses automated method and apparatus for the continuous or semi-continuous production of contact lenses.

As noted in the prior response, Martin et al. also discloses

“Accumulator section 168 includes a holding mechanism 166 that is timed by a control means (not shown) to halt a lead pallet in place on the conveyor 32(c) and enable a predetermined number of subsequent pallets to assemble behind the halted lead pallet to enable batch processing at the procure apparatus. In the preferred embodiment, twelve pallets are accumulated enabling up to ninety-six (96) mold assemblies to be processed at the procure apparatus 60 in a batch mode for an extended period of time of 30 to 60 seconds while continuously receiving new pallets from the production line at a rate of 1 every 6 to 12 seconds.” Column 32, lines 51-65.

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According to Martin et al. the accumulator holds new pallets until 12 are accumulated. If pallets arrive every 6 to 12 seconds, that means the lenses can be held at the accumulator from between 72 to 144 seconds. Examiner has stated that the “timeframe takes the maximum number of lenses suggested by Martin et al, into account (“up to ninety-six”). In this “up-to” embodiment, about half of the lenses would continue to have a dwell time of less than about 45 seconds.” What Martin et al. says is:

“twelve pallets are accumulated enabling *up to ninety-six (96) mold assemblies* to be processed at the precure apparatus”. Col. 32, lines 61-62. The phrase “up to” refers to the number of mold assemblies in each pallet, not the number of pallets being collected in the accumulating section. Even if each pallet is half full, the lenses will still be held in the accumulating section for the time periods disclosed in Martin et al. (72 to 144 seconds).

The cited references recognize neither the problem nor the solution identified by the Applicants, namely that “[d]well time, or the elapsed time from which the monomer mixture is dispensed into the mold until curing commences is critical because the coating composition is soluble in the hydrogel and silicone-containing hydrogel monomer mixtures.” Page 16, lines 28-31.

Applicants respectfully submit that claim 7 is patentable over the combination of Winteron, et al., Vanderlaan et al. and Martin et al.

Claims 9 and 10 are patentable over Winterton et al. in view of Martin et al. and Li et al (US 6,565,776).

Li et al discloses “using inorganic material to coat the optical surfaces and sidewalls of mold parts made from clear-resin materials”. The coating materials protect “the clear resin from interaction with otherwise reactive monomers from which the molded article is made, such coatings can also be used to achieve preferential release.” Li et al. abstract. Thus the coatings of

Li et al. remain on the lens mold and do not become part of the contact lens. Li et al. discloses neither processes for making coated contact lenses, coating polymers having the specified molecular weights nor the recited dwell times. Thus, Li et al. does not cure the deficiencies of the previously discussed references. Reversal of the rejection of claims 9 and 10 as unpatentable over Winterton et al., in view of Martin et al. and Li et al. is requested.

Claim 11 is patentable over Winterton et al. in view of Martin et al. and Soye et al (US 5,316,700).

Claim 11 depends indirectly from claim 1.

Soye et al. et al discloses “providing [a] cavity for excess lens forming material with at least two openings and producing differential gas pressure across the opening to remove excess lens forming material.” Soye et al. abstract. Soye et al. does not disclose methods for forming coated contact lenses, the desired molecular weights for the coating polymer or dwell times useful therefore. Thus, Soye et al. does not cure the deficiencies of the previously discussed references. Reversal of the rejection of claim 11 as unpatentable over Winterton et al., in view of Martin et al. and Soye et al. is requested.

Claims 14-18, 23, 64-66, 68-71 and 74 are patentable over Winterton et al. in view of Martin et al. and Yang et al (US5,397,848) and Lohmann et al (US 6,169,127).

Winterton et al. specifically discloses that the coatings described therein are polyionic. PolyHEMA is a non-ionic polymer.

Examiner stated that Yang et al. “suggest poly(acrylic acid), poly(methacrylic acid) and poly(hydroxyethyl methacrylate) are suitable and equivalent alternative hydrophilic materials.” This is incorrect. Yang et al. discloses that poly(acrylic acid), poly(methacrylic acid) and poly(hydroxyethyl methacrylate) are examples of hydrophilic *moieties* which may be used as the hydrophilic portion of a silicone-hydrophilic copolymer. See col.1, lines 63-66 which discloses processes “for incorporating a hydrophilic constituent into a silicone polymer material comprise

introducing a hydrophilic component including a hydrophilic portion and a silicone portion into a silicone polymeric material.” “It is believed that the silicone polymer portion of the presently useful hydrophilic constituents, e.g., the hydrophilic component itself, often have sufficiently high molecular weight so as to facilitate the physical immobilization of the hydrophilic component in the silicone polymer material.” Col. 3, lines 27-31. Thus Yang et al. does not disclose polyHEMA as suggested by the Examiner, but instead silicone-polyHEMA copolymers, which contain “silicone polymer portions of sufficiently high molecular weight so as to facilitate physical immobilization.” Silicone-polyHEMA copolymers of this type are not recited in claim 14 of the present claims.

Lohmann et al. discloses coating an article via “after-glow plasma-induced polymerization of a *polymerizable unsaturated* compound on the substrate”. Col. 7, lines 4-5. Lohman et al. teaches that the “expressions ‘polymerizable unsaturated compound’ and monomer are used . . . synonymously”. Col 7, lines 23-25. Lohmann et al. further discloses at column 11, lines 5-15 that hydroxyethylmethacrylate is a suitable *monomer* which may be used in the after- glow plasma-induced coatings disclosed therein. Thus, Lohmann et al. discloses a reactive process for forming coatings from *reactive monomers*. Lohmann et al. also discloses that the substrate “includes any material conventionally used for the manufacture of biomedical devices, e.g. contact lenses, which are hydrophilic per se, sans reactive groups, e.g. amine or hydroxyl groups are inherently present in the material and therefore also at the surface of a biomedical device . . . but suitable materials may also be based on other underlying monomers or polymers having reactive groups.” Column 10, lines 16-29. Thus, there is nothing in Lohmann et al. which suggests using any polymeric material as a coating composition. Instead Lohmann et al. discloses forming a polymeric coating, by polymerizing reactive monomers onto a lens surface which has reactive groups.

Winterton et al. requires that the coating compositions disclosed therein contain at least one polyionic material. “As used herein, a ‘polyion’ or ‘polyionic material’ refers to a polymeric material that has a plurality of charged groups”. Col. 9, lines 22-24.

Winterton et al. discloses that the polyionic materials are critical as, to build coatings having the desired thickness, multiple coatings having alternating charges are used. See, for example, column 3, lines 32-47. PolyHEMA is a non-ionic polymer. There is nothing in either Yang et al. or Lohmann et al. which would suggest that polyHEMA is equivalent to ionic polymers such as poly(methacrylic acid) or poly(acrylic acid) when an ionic polymer required.

“It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.” *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443; 230 U.S.P.Q. 416 (Fed. Cir. 1986)

Claims 15-18, 23, 64-66, 68-71 and 74 all depend from claim 14, and are patentable for the reasons discussed above. Reversal of the rejection of claims 14-18, 23, 64-66, 68-71 and 74 as unpatentable over Winterton et al., in view of Martin et al., Yang et al. and Lohmann et al. is requested.

Claims 19 and 20 are patentable over Winterton et al. in view of Martin et al. and Yang et al., Lohmann et al., and in further view of Turner et al. (WO 01/27662).

Claims 19 and 20 depend indirectly from claim 14, and are thus patentable for all the reasons discussed above. Turner et al. discloses that the “coatings are prepared and applied as aqueous solutions, suspensions, or colloids and then applied to the substrate”, page 8, lines 5-7. Thus, regardless of the substrate polymers disclosed by Turner et al., its disclosure does not cure the deficiencies of the combination of Winterton et al., Martin et al., Yang et al., Lohmann et al. Reversal of the rejection of claims 19 and 20 as unpatentable over Winterton et al., in view of Martin et al., Yang et al. and Lohmann et al. is requested.

Claims 24 and 25 are patentable over Winterton et al. in view of Martin et al., Yang et al. Lohmann et al and Li (US 6,565,776).

Examiner also maintain the rejection of claims 24 and 25 stating that Li discloses that spin coating is a recognized technique for coating a contact lens mold. Claims 24 and 25 depend indirectly from claim 14. Even if Li et al. is taken to disclose spin coating as a recognized technique, as discussed above with respect to claim 14, the combination of Winterton et al., Martin et al., Yang et al. and Lohmann et al. fail to suggest using polyHEMA to coat a lens mold and form a coating which is not chemically attached to the lens. Accordingly, claims 24 and 25 are patentable for the same reasons as claim 14. Reversal of the rejection of claims 19 and 20 as unpatentable over Winterton et al., in view of Martin et al., Yang et al., Lohmann et al. and Li et al. is requested.

Claim 26 is patentable over Winterton et al. in view of Martin et al., Yang et al. Lohman et al., Li et al. and Soye et al.

Examiner further rejected claim 26 as unpatentable over Winterton et al. in view of Martin et al., Yang et al. Lohman et al., Li et al. and Soye et al. Claim 26 depends indirectly from claim 14. As discussed above with respect to claim 14, the combination of Winterton et al., Martin et al., Yang et al. and Lohman et al. fail to suggest using polyHEMA to coat a lens mold and form a coating which is not chemically attached to the lens. Soye et al. et al discloses "providing [a] cavity for excess lens forming material with at least two openings and producing differential gas pressure across the opening to remove excess lens forming material." Soye et al. abstract. Soye et al. does not disclose methods for forming coated contact lenses, the desired molecular weights for the coating polymer or dwell times useful therefore. Soye et al. does not disclose any of these elements. Accordingly, claim 26 is patentable for the same reasons as claim 14. Reversal of the rejection of claim 26 as unpatentable over Winterton et al., in view of Martin et al., Yang et al., Lohmann et al., Li et al. and Soye et al. is requested.

Claims 31,32,36,38,76-78, 80-83, 85 and 86 are patentable over Winterton et al. in view of Martin et al. and Vanderlaan et al.

Claim 31 is an independent claim and recites a method for manufacturing a contact lens comprising by coating a mold surface with a hydrophilic coating composition having a molecular weight of greater than about 300 kD; dispensing a silicone containing monomer mixture into the coated mold, exposing the filled mold to a dwell time of less than about 45 seconds, forming the contact lens and said coating composition does not chemically attach to the article.

As discussed above with respect to claim 1, the references taken as a whole fail to disclose or suggest a process having the recited combination of coating molecular weight, dwell time and lack of chemical attachment. Moreover, the Examiner's assumptions about what Winterton et al. teaches about the selection of molecular weight and the "dwell times" inherently possessed by Martin et al. have been clearly rebutted above. Also, as discussed above with respect to claim 7, Martin et al. does not disclose dwell times of less than about 45 seconds, as the accumulator holds lenses for longer than that time period. As discussed above with respect to amended claim 1, the references taken as a whole fail to discuss a process having the recited combination of coating molecular weight, dwell time and lack of chemical attachment. Moreover, the Examiner's assumptions about what Winterton et al. teaches about the selection of molecular weight and the "dwell times" inherently possessed by Martin et al. have been clearly rebutted above. A prima facie case of obviousness has not been made. Reversal of the rejections based upon claims 31, 32, 36, 38, 76-78, 80-83, 86 and 86 is requested.

Claims 34 and 35 are patentable over Winterton et al. in view of Martin et al. and Vanderlaan et al. and Turner et al.

Claims 34 and 35 depend indirectly from claim 31, and are thus patentable for all the reasons discussed above. Turner et al. discloses that the "coatings are prepared and applied as

aqueous solutions, suspensions, or colloids and then applied to the substrate", page 8, lines 5-7. Thus, regardless of the substrate polymers disclosed by Turner et al., its disclosure does not cure the deficiencies of the combination of Winterton et al., Martin et al. and Vanderlaan et al. Reversal of the rejection of claims 34 and 35 over the cited combination of references is requested.

Claim 37 is patentable over Winterton et al. in view of Martin et al. and Vanderlaan et al., Yang et al. and Holguin et al. (US6,706,836).

Holguin et al. discloses a method for preparing poly 2-hydroxyethyl methacrylate and pressure sensitive adhesives. There is nothing in Holguin et al. which would suggest that a non-ionic polymer such as polyHEMA could be used in a coating process where an ionic polymer is required, or that a polymer having a molecular weight twice that disclosed in Winterton et al. would be useful in that process. Accordingly, claim 37 is patentable over the combination of Winterton et al. in view of Martin et al., Vanderlaan et al., Yang et al. and Holguin et al.

Claims 39 and 40 are patentable over Winterton et al. in view of Martin et al., Vanderlaan et al. and Li et al. Claim 41 is patentable over Winterton et al. in view of Martin et al., Vanderlaan et al., Li et al. and Soye et al.

Claims 39, 40 and 41 depend indirectly from claim 31. As discussed above with respect to claim 31, the combination of Winterton et al., Martin et al. and Vanderlaan et al. fail to suggest coating processes comprising hydrophilic coating composition having a molecular weight of greater than about 300 kD which are coated on a mold surface; a dwell time of less than about 45 seconds and said coating composition does not chemically attach to the article. Neither Soye et al. nor Li et al. disclose any of these elements. Accordingly, claims 39, 40 and 41 are patentable for the same reasons as claim 31.

Claims 55, 60 and 63 are patentable over Winterton et al. in view of Martin et al., and Narducy et al. (US 4,963,159).

In making the rejection Examiner applied Winterton et al. and Martin et al. as applied to claim 1 and cited Narducy et al. as a reference to disclose ethanol as a solvent and ethyl lactate as a cosolvent. Claims 55, 60 and 63 depend indirectly from claim 1, which has been amended to recite that the coating polymer has a molecular weight of greater than about 300 kD. Narducy et al. does not disclose applying the color coat to the lens mold, or the molecular weight of the binding polymer. Thus Narducy et al. fails to disclose or suggest a mold transfer process, the molecular weight of the binding polymer necessary for such a process, or the dwell time required by the combination of the process and binding polymer molecular weight.

Thus, claims 55, 60 and 63 are patentable for the reasons discussed above with respect to claim 1. Reversal of the rejections is requested.

Claims 67, 72 and 75 are patentable over Winterton et al., Martin et al., Yang et al., Lohmann et al. and Narducy et al.

In making the rejection Examiner applied Winterton et al., Martin et al., Yang et al., Lohmann et al as applied to claims 14-18, 23, 64-66, 68-71, 73 and 74 and cited Narducy et al. as a reference to disclose ethanol as a solvent and ethyl lactate as a cosolvent. Claims 67, 72 and 75 depend indirectly from claim 14. As discussed above with respect to claim 14, Winterton et al. requires the polymers used in its coating process are polyioinic. PolyHEMA is a non-ionic polymer, and there is nothing in either Yang et al. or Lohmann et al. which would suggest that polyHEMA is equivalent to ionic polymers such as poly(methacrylic acid) or poly(acrylic acid) when an ioinic polymer is required. Narducy et al. does not cure this deficiency. Accordingly,

claims 67, 72 and 75 are patentable for the reasons discussed with respect to claim 14. Reversal of the rejections is requested.

Claims 79, 84 and 87 are patentable over Winterton et al., Martin et al., Vanderlaan et al. and Narducy et al.

Claims 79, 84 and 87 of the present invention depend from claim 38. Claim 79 further recites that the colorant composition comprises ethanol as a low boiling point solvent and ethyl lactate as a high boiling point solvent. Claim 84 recites ethyl lactate as a high boiling solvent. Claim 87 recites the low boiling point solvent and the high boiling point solvent are present at a ratio of about 1:1.

As discussed above, Naducy et al. discloses a process for making colored contact lenses. Abstract. Narducy et al. discloses that the color coat contains a solvent (col. 5, lines 4-9), which may be ethanol as a solvent and ethyl lactate as a cosolvent. Col. 5, lines 10-13. However, Narducy et al. does not disclose applying the color coat to the lens mold, or the molecular weight of the binding polymer. Thus Narducy et al. fails to disclose or suggest a mold transfer process, the molecular weight of the binding polymer necessary for such a process, or the dwell time required by the combination of the process and binding polymer molecular weight.

As discussed above with respect to amended claim 1, the references taken as a whole fail to disclose a process having the recited combination of coating molecular weight, dwell time and lack of chemical attachment. Narducy et al. does not cure this deficiency. Accordingly, claims 79, 84 and 87 are patentable for the reasons discussed with respect to claims 31, 32, 36, 38, 76-78, 80-83, 85 and 86. Reversal of the rejections is requested.

CONCLUSION

For the foregoing reasons, the reversal of the rejections relating to the claims is respectfully requested.

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11. **APPENDIX OF CLAIMS INVOLVED IN THE APPEAL**

1. **(Rejected)** A method for manufacturing an article comprising the steps of: a.) coating a molding surface of a mold or a mold half with a coating effective amount of a high molecular weight coating composition having a molecular weight of greater than about 300 kD and comprising at least one polymer selected from the group consisting of poly(vinyl alcohol), polyethylene oxide, poly(2-hydroxyethyl methacrylate), poly(acrylic acid), poly(methacrylic acid), poly(maleic acid), poly(itaconic acid), poly(acrylamide), poly(dimethylacrylamide), carboxymethylated polymers, polystyrene sulfonic acid, polysulfonate polymers, polysaccharides, glucose amino glycans, block or random copolymers thereof, or mixtures thereof; b.) dispensing a monomer mixture comprising, a silicone-containing hydrogel monomer, into the mold or mold half; and c.) curing the monomer mixture and the coating composition using a dwell time of less than about 5 minutes and under conditions suitable to form an article coated with the coating composition; wherein said at least one polymer does not chemically attach to the article.
2. **(Rejected)** The method of claim 1, wherein the article is a contact lens.
3. **(Rejected)** The method of claim 1 or 2, wherein the monomer mixture further comprises at least one hydrogel monomer.
4. **(Canceled).**
5. **(Canceled).**
6. **(Rejected)** The method of claim 1, wherein the dwell time is less than about 45 seconds.

7. **Canceled.**
8. **(Rejected)** The method of claim 1, wherein the coating composition further comprises a low boiling point solvent and a high boiling point solvent.
9. **(Rejected)** The method of claim 8, wherein the coating of the molding surface is carried out by spin coating.
10. **(Rejected)** The method of claim 9, wherein spin coating is carried out using at least about 2 μ l and no more than about 20 μ l of the coating composition.
11. **(Rejected)** The method of claim 10, further comprising applying, subsequent to the spin coating step, a pressurized air jet to an edge of the mold.
12. **(Withdrawn.)** An article formed by the method of claim 1, 6, 7, or 9.
13. **(Withdrawn.)** A contact lens formed by the method of claim 2.
14. **(Rejected)** A method for manufacturing an article comprising: a.) coating a molding surface of a mold or a mold half with a coating effective amount of a high molecular weight hydrophilic coating composition comprising poly(2-hydroxyethyl methacrylate).; b.) dispensing a monomer mixture comprising a hydrogel monomer, silicone-containing hydrogel monomer, or combination thereof into the mold or mold half; and c.) curing the monomer mixture and coating composition using a dwell time of less than about 5 minutes and under conditions suitable to form an article coated with the coating composition wherein said coating composition does not chemically attach to the article.

15. **(Rejected)** The method of claim 14, wherein the article is a contact lens.
16. **(Rejected)** The method of claim 15, wherein the monomer mixture comprises a hydrogel monomer.
17. **(Rejected)** The method of claim 15, wherein the monomer mixture comprises a silicone hydrogel monomer.
18. **(Rejected)** The method of claim 14, wherein the dwell time is less than about 45 seconds.
19. **(Rejected)** The method of claim 17, wherein the silicone hydrogel monomer mixture comprises a reaction product of a silicone based macromer Group Transfer Polymerization product and a polymerizable mixture comprising Si_{8-10} monomethacryloxy terminated polydimethyl siloxane, polydimethylsiloxane other than Si_{8-10} monomethacryloxy terminated polydimethyl siloxane, and a hydrophilic monomer.
20. **(Rejected)** The method of claim 19, wherein the silicone hydrogel monomer mixture comprises the macromer in an amount of about 15 to about 25 wt percent, the Si_{8-10} monomethacryloxy terminated polydimethyl siloxane in an amount of about 20 to about 30 wt percent; methacryloxypropyl tris(trimethyl siloxy) silane in an amount of about 15 to about 25 wt percent; N,N-dimethyl acrylamide in an amount of about 20 to about 30 wt percent; 2-hydroxy ethyl methacrylate in an amount of about 2 to about 7 wt percent; tetraethyleneglycol dimethacrylate in an amount of about 0 to about 5 wt percent and poly(N-vinyl pyrrolidinone) in an amount of about 0 to about 5 weight percent.

- 21. **(Canceled)**
- 22. **(Canceled.)**
- 23. **(Rejected)** The method of claim 15, wherein the coating composition further comprises a low boiling point solvent and a high boiling point solvent.
- 24. **(Rejected)** The method of claim 23, wherein the coating of the molding surface is carried out by spin coating.
- 25. **(Rejected)** The method of claim 24, wherein spin coating is carried out using at least about 2 μ l and no more than about 20 μ l of the coating composition.
- 26. **(Rejected)** The method of claim 25, further comprising applying, subsequent to the spin coating step, a pressurized air jet to an edge of the mold.
- 27. **(Withdrawn.)** An article formed by the method of claim 14.
- 28. **(Withdrawn.)** A contact lens formed by the method of claim 15, 18, 19, or 20.
- 29. **(Withdrawn.)** A contact lens formed by the method of claim 21.
- 30. **(Withdrawn.)** A contact lens formed by the method of claim 22.
- 31. **(Rejected)** A method for manufacturing contact lenses comprising: a.) coating a molding surface of a mold or a mold half with a coating effective amount of a hydrophilic coating composition having a molecular weight of greater than about 300 kD; b.) dispensing a mixture

comprising a silicone-containing hydrogel monomer into the mold or mold half; and c.) curing the mixture and coating composition using a dwell time of less than about 45 seconds and under conditions suitable to form a contact lens coated with the coating composition, wherein the formed lens exhibits physiological compatibility and said coating composition does not chemically attach to the article.

32. **(Rejected)** The method of claim 31, wherein the mixture further comprises at least one hydrogel monomer.

33. **(Canceled.)**

34. **(Rejected)** The method of claim 31, wherein the silicone hydrogel monomer mixture comprises a reaction product of a silicone based macromer Group Transfer Polymerization product and a polymerizable mixture comprising Si_{8-10} monomethacryloxy terminated polydimethyl siloxane, polydimethylsiloxane other than Si_{8-10} monomethacryloxy terminated polydimethyl siloxane, and a hydrophilic monomer.

35. **(Rejected)** The method of claim 34, wherein the silicone hydrogel monomer mixture comprises the macromer an amount of about 15 to about 25 wt percent, the Si_{8-10} monomethacryloxy terminated polydimethyl siloxane in an amount of about 20 to about 30 wt percent; methacryloxypropyl tris(trimethyl siloxy) silane in an amount of about 15 to about 25 wt percent; N,N-dimethyl acrylamide in an amount of about 20 to about 30 wt percent; 2-hydroxy ethyl methacrylate in an amount of about 2 to about 7 wt percent; tetraethyleneglycol dimethacrylate in an amount of about 0 to about 5 wt percent and poly(N-vinyl pyrrolidinone) in an amount of about 0 to about 5 weight percent.

36. **(Rejected)** The method of claim 31, 32, 34, or 35, wherein the coating composition comprises poly(vinyl alcohol), polyethylene oxide, poly(2-hydroxyethyl methacrylate), poly(acrylic acid), poly(methacrylic acid), poly(maleic acid), poly(itaconic acid), poly(acrylamide), poly(dimethacrylamide), carboxymethylated polymers, polystyrene sulfonic acid, polysulfonate polymers, polysaccharides, glucose amino glycans, block or random copolymers thereof, or mixtures thereof.
37. **(Rejected)** The method of claim 36, wherein the coating composition comprises poly(2-hydroxyethyl methacrylate).
38. **(Rejected)** The method of claim 36, wherein the coating composition further comprises a low boiling point solvent and a high boiling point solvent.
39. **(Rejected)** The method of claim 38, wherein the coating of the molding surface is carried out by spin coating.
40. **(Rejected)** The method of claim 39, wherein spin coating is carried out using at least about 2 μ l and no more than about 20 μ l of the coating composition.
41. **(Rejected)** The method of claim 40, further comprising applying, subsequent to the spin coating step, a pressurized air jet to an edge of the mold.
42. **(Withdrawn.)** A contact lens formed by the method of claim 31, 32, 33, 34, or 35.
43. **(Withdrawn.)** A contact lens formed by the method of claim 36.
44. **(Withdrawn.)** A contact lens formed by the method of claim 37.

45. **(Withdrawn.)** A contact lens formed by the method of claim 38.
46. **(Withdrawn.)** A contact lens formed by the method of claim 39.
47. **(Withdrawn.)** The contact lens of claim 42, wherein the coating composition comprises a coating of a dry film thickness of not less than about 5 nm and not more than about 70 nm.
48. **(Withdrawn.)** The contact lens of claim 43, wherein the coating composition comprises a coating of a dry film thickness of not less than about 5 nm and not more than about 70 nm.
49. **(Withdrawn.)** The contact lens of claim 44, wherein the coating composition comprises a coating of a dry film thickness of not less than about 5 nm and not more than about 70 nm.
50. **(Withdrawn.)** The contact lens of claim 45, wherein the coating composition comprises a coating of a dry film thickness of not less than about 5 nm and not more than about 70 nm.
51. **(Withdrawn.)** The contact lens of claim 4, wherein the coating composition comprises a coating of a dry film thickness of not less than about 5 nm and not more than about 70 nm.
52. **(Rejected)** The method of claim 1 wherein the coating composition has a viscosity of about 17.7 cP at 25°C.
53. **(Rejected)** The method of claim 1 wherein the coating composition has a viscosity of at least about 4 cP at 25°C.

54. **(Rejected)** The method of claim 1 wherein the coating composition has a viscosity of greater than about 1 cP at 25°C.
55. **(Rejected)** The method of claim 8 wherein the low boiling point solvent comprises ethanol and the high boiling point solvent comprises ethyl lactate.
56. **(Rejected)** The method of claim 8 wherein the low boiling point solvent has a boiling point of less than about 90°C.
57. **(Rejected)** The method of claim 8 wherein the low boiling point solvent comprises ethanol.
58. **(Rejected)** The method of claim 8 wherein the low boiling point solvent is selected from the group consisting of n-methyl pyrrolidone, acetone, chloroform, methanol, ethanol, isopropanol, tert-butanol and combinations thereof.
59. **(Rejected)** The method of claim 8 wherein the high boiling point has a boiling point of greater than about 100°C.
60. **(Rejected)** The method of claim 8 wherein the high boiling point solvent comprises ethyl lactate.
61. **(Rejected)** The method of claim 8 wherein the high boiling point solvent is selected from the group consisting of methyl lactate, ethyl lactate, isopropyl lactate, ethylene glycol, polyethylene glycol, propylene glycol, dimethyl formamide, tetrahydrogeraniol, 1-butanol, 1-pentanol, 1-hexanol, 1-octanol, 3-methyl-3-pentanol, dimethyl-3-octanol, 3-methoxy-1-butanol, 1,2-butanediol, 1,4-butanediol, 1,3-hexanediol, water and combinations thereof.

62. **(Rejected)** The method of claim 8 wherein the low boiling point solvent and the high boiling point solvent are present at a ratio of about 1:1.
63. **(Rejected)** The method of claim 55 wherein the low boiling point solvent and the high boiling point solvent are present at a ratio of about 1:1.
64. **(Rejected)** The method of claim 14 wherein the coating composition has a viscosity of about 17.7 cP at 25°C.
65. **(Rejected)** The method of claim 14 wherein the coating composition has a viscosity of at least about 4 cP at 25°C.
66. **(Rejected)** The method of claim 14 wherein the coating composition has a viscosity of greater than about 1 cP at 25°C.
67. **(Rejected)** The method of claim 23 wherein the low boiling point solvent comprises ethanol and the high boiling point solvent comprises ethyl lactate.
68. **(Rejected)** The method of claim 23 wherein the low boiling point solvent has a boiling point of less than about 90°C.
69. **(Rejected)** The method of claim 23 wherein the low boiling point solvent comprises ethanol.
70. **(Rejected)** The method of claim 23 wherein the low boiling point solvent is selected from the group consisting of n-methyl pyrrolidone, acetone, chloroform, methanol, ethanol, isopropanol, tert-butanol and combinations thereof.

71. **(Rejected)** The method of claim 23 wherein the high boiling point has a boiling point of greater than about 100°C.
72. **(Rejected)** The method of claim 23 wherein the high boiling point solvent comprises ethyl lactate.
73. **(Rejected)** The method of claim 23 wherein the high boiling point solvent is selected from the group consisting of methyl lactate, ethyl lactate, isopropyl lactate, ethylene glycol, polyethylene glycol, propylene glycol, dimethyl formamide, tetrahydrogeraniol, 1-butanol, 1-pentanol, 1-hexanol, 1-octanol, 3-methyl-3-pentanol, dimethyl-3-octanol, 3-methoxy-1-butanol, 1,2-butanediol, 1,4-butanediol, 1,3-hexanediol, water and combinations thereof.
74. **(Rejected)** The method of claim 23 wherein the low boiling point solvent and the high boiling point solvent are present at a ratio of about 1:1.
75. **(Rejected)** The method of claim 67 wherein the low boiling point solvent and the high boiling point solvent are present at a ratio of about 1:1.
76. **(Rejected)** The method of claim 31 wherein the coating composition has a viscosity of about 17.7 cP at 25°C.
77. **(Rejected)** The method of claim 31 wherein the coating composition has a viscosity of at least about 4 cP at 25°C.
78. **(Rejected)** The method of claim 31 wherein the coating composition has a viscosity of greater than about 1 cP at 25°C.

79. **(Rejected)** The method of claim 38 wherein the low boiling point solvent comprises ethanol and the high boiling point solvent comprises ethyl lactate.
80. **(Rejected)** The method of claim 38 wherein the low boiling point solvent has a boiling point of less than about 90°C.
81. **(Rejected)** The method of claim 38 wherein the low boiling point solvent comprises ethanol.
82. **(Rejected)** The method of claim 38 wherein the low boiling point solvent is selected from the group consisting of n-methyl pyrrolidone, acetone, chloroform, methanol, ethanol, isopropanol, tert-butanol and combinations thereof.
83. **(Rejected)** The method of claim 38 wherein the high boiling point has a boiling point of greater than about 100°C.
84. **(Rejected)** The method of claim 38 wherein the high boiling point solvent comprises ethyl lactate.
85. **(Rejected)** The method of claim 38 wherein the high boiling point solvent is selected from the group consisting of methyl lactate, ethyl lactate, isopropyl lactate, ethylene glycol, polyethylene glycol, propylene glycol, dimethyl formamide, tetrahydrogeraniol, 1-butanol, 1-pentanol, 1-hexanol, 1-octanol, 3-methyl-3-pentanol, dimethyl-3-octanol, 3-methoxy-1-butanol, 1,2-butanediol, 1,4-butanediol, 1,3-hexanediol, water and combinations thereof.
86. **(Rejected)** The method of claim 38 wherein the low boiling point solvent and the high boiling point solvent are present at a ratio of about 1:1.

87. **(Rejected)** The method of claim 79 wherein the low boiling point solvent and the high boiling point solvent are present at a ratio of about 1:1.

12. **EVIDENCE APPENDIX**

None.

13. **RELATED PROCEEDINGS APPENDIX**

None.